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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,598	09/23/2005	Thomas J. Guttuso Jr	176/61332	7385

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EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,598	GUTTUSO JR, THOMAS J.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49 and 51-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49,51-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The response filed **1/30/08** presents remarks and arguments to the office action mailed **10/31/07**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Response to Argument:

Applicant argues that claims 49 and 51-56 as rejected over Levinson et al in view of vitamin world do not teach the claimed invention because Levinson et al. provide improved nutritional support for premenopausal women and that the composition includes other components and a long list of amino acids and that the reference fail to show how much of methionine is needed to treat hot flash.

In Response, the claim language of instant claim 49 recites "comprising" which means other components are not excluded from the composition. The Levinson reference teaches a nutritional composition for the treatment of symptoms associated with hotfash and list methionine as one of the aminoacids. One of ordinary skill in the

art would be motivated to try either a single unit tablet of the claimed invention or use the composition as it is given in Levinson et al.

With regards to the "obvious to try", the claimed invention would have been obvious to try in view of the fact that the courts have held that "an invention is obvious to try" where the prior art gives either no indication of which parameters are critical or no direction as to which of many possible choices is likely to be successful, Merck & Co V. Biocraft Laboratories Inc., 10 USPQ2D 1813(Fed. Cir. 1919); In re O'Farrel, 7USPQ2D 1673, 1681 (Fed. Cir. 1988).

With regards to picking from a wide variation of list, it is obvious to do so as this is a rejection under 103 and not 102. The art clearly teaches the use of the compound and the combination of the art is obvious. As to the concentration, claim 49 only recited an effective amount. Methionine is sold in the effective amount that is needed in the dependent claims to treat hotfash,therefore one of ordinary skill in the art would be motivated to use a concentration taught by vitaminworld.

Careful consideration has been given and the rejection is maintained as in the last office action of record.

Claims 49 and 51-56 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Levinson et al., US 6479,545 in view of http://www.vitaminworld.com/pages/file (of record).

Levinson et al. teach administering a composition which provide improved nutritional support for the relief of symptoms associated with menopause. See

abstract, where in the composition comprises methionine as required by instant claim 49. See co. 14, lines 65-67.

http://www.vitaminworld.com/pages/file, Vitamin world sells L-methioninine as single unit in tablet forms of 500 mg as required by instant claims 49-56.

The difference between the instant application and Levinson et al. reference is that Levinson et al. do not expressly teach the L-form of methionine.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the L-form of methionine, as suggested by Vitaminworld, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because L-methionine is a protein amino acid, classified as an essential amino acid and therefore must be supplied in that form. Therefore one of ordinary skill in the art would have been motivated to combine the teaching of the prior art and administer methionine to patients suffering from hot flash because the prior art teaches methionine is administered to patients suffering from menopausal symptoms. One such symptom is hot flash absent factual evidence.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

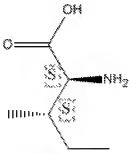
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

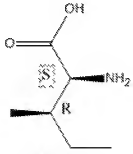
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 49, 51-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gollobin, US 6,245,812 in view of Mamer et al. J. Mass Spect. 31, 1382-1388 as evident by chemdrawing (compounds are illustrated below from the use of chemdraw).

Gollobin teach a method of treating hotflash administering a compositon comprising isoleucine. See Abstract. Isoleucine is a stereoisomer of alloisoleucine. As



isoleucine



alloisoleucine

evident by Chemdraw isoleucine and alloisoleucine are stereoisomers. The reference teaches the effective amount of isoleucine is 150-700 mg that is orally administered in a pharmaceutically acceptable carrier as a solid or liquid dosage form and as a nutritional supplement as required by instant claims 51-63. See col 3, lines 9-45.

It would have been obvious to one of ordinary skill in the art to have used alloisoleucine in place of isoleucine because it is known in the art that L-isoleucine and L-alloisoleucine are slowly interconvertible in living organism as taught by Mamer et al. Thus one of ordinary skill in thee art would have been motivated to substitute isoleucine with alloisoleucine and expect the same result because it is known in the art to interconvert from one form to another. See underlining Mamer et al.

Claims 49, 50-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gollobin, US 6,245,812 in view of Mamer et al. J. Mass Spect. 31, 1382-1388, 1996 and Paolo et al. Menopause 8(4):252-258, 2001 as evident by chemdrawing (compounds are illustrated below from the use of chemdraw) As evident by http://www.imaginis.com/breasthealth/hrt.asp (womens' health).

.Gollobin, marmer are applied here as above.

Paolo et al teach administering L-methionine to post-menopausal women for the treatment of hormone replacement therapy. As evident by http://www.imaginis.com/breasthealth/hrt.asp (Women's health) hormone replacement therapy is given as decreased levels of estrogen causes hot flash. See underlined.

Thus one of ordinary skill in the art would be motivated to combine the above cited art with that of Paolo et al and administer a composition comprising isoleucine/alloisoleucine with methionine or administer the compounds alone to treat hot flash because the compounds are taught in the art to be given for treating hot flash.

Claims 64-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paolo et al. Menopause 8(4):252-258, 2001 in view of Gollobin, US 6,245,812 and as evident by http://www.imaginis.com/breasthealth/hrt.asp (Women's health) July 2001 and http://www.vitaminworld.com/pages/file (of record).

Paolo et al teach administering L-methionine to post-menopausal women for the treatment of hormone replacement therapy. As evident by http://www.imaginis.com/breasthealth/hrt.asp (Women's health) hormone replacement

therapy is given as decreased levels of estrogen causes hot flash in an amount of 0.1g/kg body weight which is within the claim limitation of instant claim 65. See underlined. The reference however did not teach the forms as a solid/liquid, having pharmaceutically acceptable carrier or in a nutrition form.

However, Gollobin teaches the forms that an aminoacid can be administered see above rejection (applies here below) art would have been motivated to administer methionine in a tablet form with suitable pharmaceutically effective carriers to treat menopause.

Thus the claim invention was prima facie obvious at the time the invention was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
4/30/08

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614